Ruchitha Sree et al, 2026, Vol.14, No.7: 155-159

International Journal of Chemistry and Pharmaceutical Sciences

https://doi.org/10.30904/j.ijcps.2026.4997 | E-ISSN: 2321-3132

Formulation and Evaluation of Tramadol Hcl Floating Tablets Using Different Polymers

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Received: 23-04-2026 | Revised: 25-05-2026 | Accepted: 08-06-2026 | Published: 09-07-2026

Abstract:

Controlled drug delivery systems have been developed which are capable of controlling the rate of drug delivery, sustaining the duration of therapeutic activity and/or targeting the delivery of drug to a tissue. A controlled drug delivery system is usually designed to deliver the drug at particular rate. Safe and effective blood levels are maintained for a period as long as the system continues to deliver the drug. Controlled drug delivery usually results in substantially constant blood levels of the active ingredient as compared to the uncontrolled fluctuations observed when multiple doses of quick releasing conventional dosage forms are administered to a patient. Hydrophilic matrix of HPMC could not control the Tramadol release effectively for more than 12 hours. Regulated drug release in first order manner attained in the current study indicates that the matrix tablets of Tramadol hydrochloride prepared using HPMC K100M can successfully be employed as a floating controlled released during delivery system.

Keywords: HPMC K100M, Tramadol Hcl, therapeutic activity, matrix tablets

Introduction

Oral drug delivery is the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage form. Oral route is considered most natural, uncomplicated, convenient and safe due to its ease of administration, patient acceptance and cost-effective manufacturing process[1]. Pharmaceutical products designed for oral delivery are mainly conventional drug delivery systems, which are designed for immediate release of drug for rapid absorption. These immediate release dosage forms have some limitations such as[2, 3].

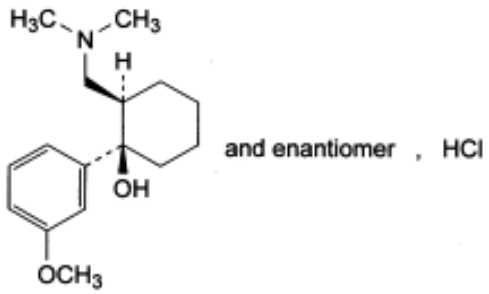

Fig.1: Tramadol hydrochloride

Molecular Formula : $C_{16}H_{26}ClNO$
Molecular Weight : 299.8
Chemical Name : (±)*cis*-2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol hydrochloride.
Content :99.0 per cent to 101.0 per cent (anhydrous substance).
Appearance : White, crystalline powder.
Solubility : Freely soluble in water and in methanol, very slightly soluble in acetone.
Melting Point : 180 °C TO 184 °C.
P^{ka} : 9.12
Water : Maximum 0.5 per cent, determined on 1.000 g.
Sulphated ash: Maximum 0.1 per cent, determined on 1.0 g.
Heavy metals *(2.4.8)*: Maximum 20 ppm.

Mechanisam of Action

Tramadol Hydrochloride is a centrally acting synthetic opioid analgesic. Although its mode of action is not completely understood, from animal tests, at least two complementary mechanisms appear applicable: binding of parent and M1 metabolite to μ-opioid receptors and weak inhibition of reuptake of nor epinephrine and serotonin. Opioid activity is due to both low affinity binding of the parent compound and higher affinity binding of the O-demethylated metabolite M1 to μ-opioid receptors. In animal models, M1 is up to 6 times more potent than Tramadol in producing analgesia and 200 times more potent in μ-opioid binding. Tramadol-induced analgesia is only partially antagonized by the opiate antagonist naloxone in several animal tests. The relative contribution of both Tramadol and M1 to human analgesia is dependent upon the plasma concentrations of each compound.

Materials and Methods

Formulation of Tramadol Hydrochloride floating tablets using different polymers HPMC K4M, HPMC K15M, HPMC K100M, Sod. Bicarbonate, Magnesium stearate, Sodium CMC, Ethyl cellulose in different ratios. Evaluation of powders of Tramadol Hydrochloride floating tablets for bulk density, tapped density, angle of repose. Compression of the powders into floating tablets of Tramadol Hydrochloride. Evaluation of floating tablets of Tramadol Hydrochloride for physical appearance, hardness, thickness, friability, weight variation, content uniformity test, and in-vitro buoyancy studies. In-vitro dissolution studies for all formulations of Tramadol Hydrochloride floating tablets. IR absorption studies have also been carried out for the pure drug and drug with polymer formulation.

Table 1: Materials used for the formulation development

1	Tramadol HCl	S.K. Parenterals Ltd.
2	HPMC K 4 M	SD Fine Chemicals Ltd.,Mumbai
3	HPMC K 15 M	SD Fine Chemicals Ltd.,Mumbai
4	HPMC K 100 M	SD Fine Chemicals Ltd.,Mumbai
5	Ethyl cellulose	SD Fine Chemicals Ltd.,Mumbai
6	Sodium.CMC	SD Fine Chemicals Ltd.,Mumbai
7	Magnesium stearate	Ranbaxy pharmaceuticals, Delhi
8	Sodium bicarbonate	SD Fine Chemicals Ltd.,Mumbai
9	Talc	SD Fine Chemicals Ltd.,Mumbai

Estimation of tramadol hydrochloride Analytical methods:
Estimation of Ranitidine Hydrochloride:
A spectrophotometric method based on the measurement of absorbance 271 nm in a 0.1 HCl was used in the present study for the estimation of Tramadol HCl.

Reagents:

Preparation of 0.1N HCl:

- 8.5ml of Concentrated HCl was taken in a volumetric flask and it was made up to 1000ml with distilled water.

Standard solution:

- 100mg of Tramadol HCl pure drug was dissolved in 100ml of water(stock solution)10ml of solution was taken and make up with100ml of water (100µg/ml). from this 10ml was taken and make up with 100 ml of water (10µg/ml).

Procedure:

- The above solution was subsequently diluted with 0.1N HCl to obtain series of dilutions Containing 2,4, 6,8, 10,20,30,40,50,60,70,80,90 and 100µg/ml of Tramadol HCl per ml of solution.
- The absorbance of the above dilutions was measured at 271 nm by using UV-Spectrophotometer taking 0.1N HCl as blank.

Preparation of Tablets
All the formulations were prepared by direct compression. The compression of different formulations are given in Table 6.The tablets were prepared as per the procedure given below and aim is to prolong the release of Tramadol Hydrochloride.

Procedure:
Tramadol HCl and all other ingredients were individually passed through sieve no 60. All the ingredients were mixed thoroughly by triturating up to 15 min. The powder mixture was lubricated with talc. The tablets were prepared by using direct compression method.

Result and Discussion

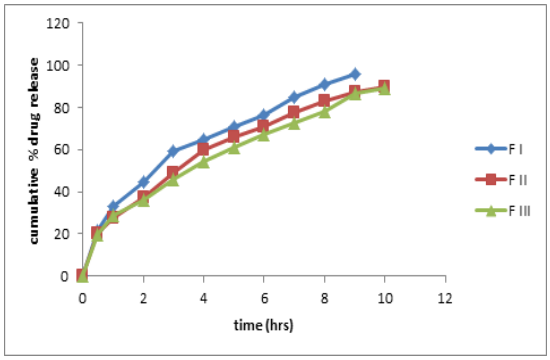

Fig.2: Dissolution profile of tramadol HCl floating tablets (F1, F2, F3 formulations)

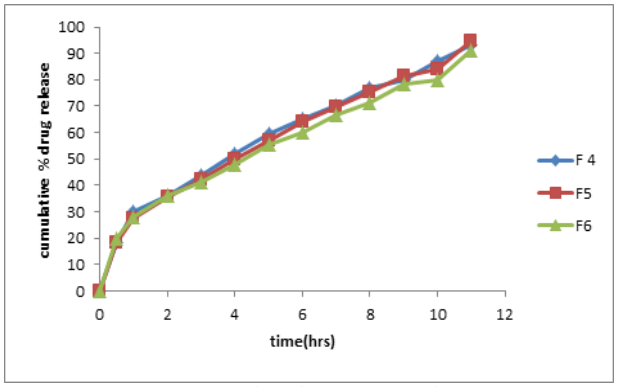

Fig.3: Dissolution profile of tramadol HCl floating tablets (F4, F5, F6 formulations).

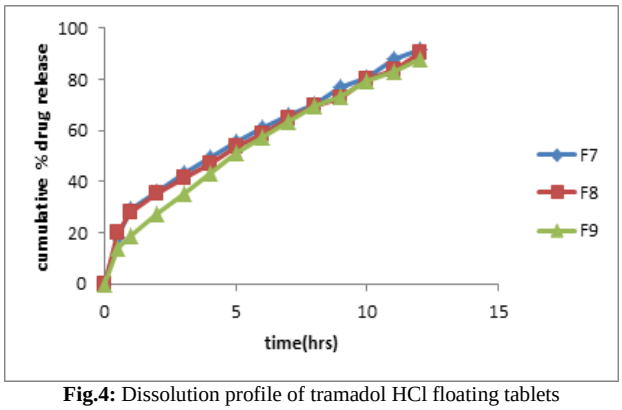

Fig.4: Dissolution profile of tramadol HCl floating tablets (F7, F8, F9 formulations).

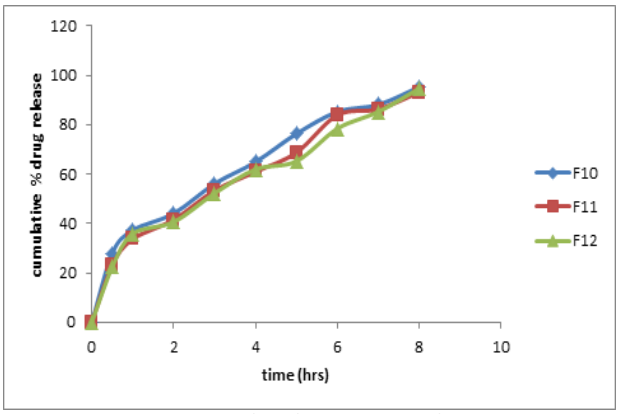

Fig.5: Dissolution profile of Tramadol HCl floating tablets (F10, F11, F12 formulations).

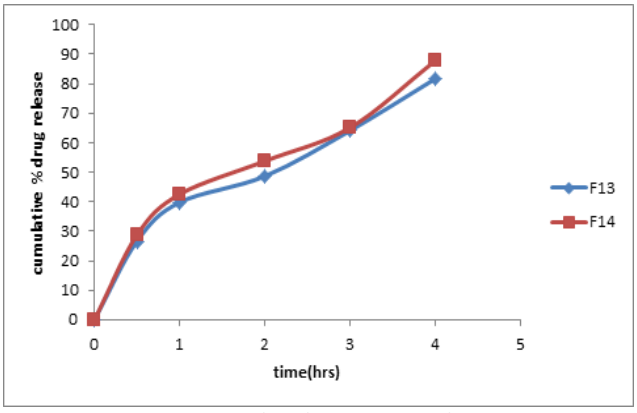

Fig.6: Dissolution profile of Tramadol HCl floating tablets (F13, F14,F15 formulations).

Table 2: Data for IR Spectra of Tramadol Hydrochloride

Functional Group	Frequency (cm^{-1})
C-H Aromatic (stretching)	3017.49
c=c Aromatic (stretching)	1404.72
C-N (stretching)	1161.78
C-H (stretching)	2860.92
CH_2 (bending)	1437.05
O-H (stretching)	3345.87

Table 3: Quality Control Parameters of Tramadol HCl floating Tablets

Formulation No.	Avg. Weight (Mean±S.D) (n=20)	Hardness (kg/cm^2) (n=3)	Friability (Mean±S.D) (n=20)	% Drug content (mg)	Buoyancy Lag time (min)	Total floating Time(hrs)	Matrix Form
F1	252±3.1	8.0±1.5	0.612	99±0.7	7.0	12	+
F2	313±2.8	8.0±2.1	0.612	100±0.5	7.2	12	+
F3	378±3.5	8.0±1.8	0.644	100±0.6	7.5	12	+
F4	251±3.1	8.0±1.5	0.611	99±0.6	6.1	12	+
F5	313±2.8	8.0±2.1	0.625	99±0.6	5.0	12	+
F6	378±3.5	8.0±2.1	0.655	99±0.5	7.4	12	+
F7	252±2.1	8.0±1.8	0.711	100±0.3	8.5	12	+
F8	313±2.8	8.0±3.0	0.702	100±0.4	8.6	12	+
F9	378±3.5	8.0±2.1	0.699	100±0.3	7.7	12	+
F10	252±3.1	8.0±3.0	0.622	99±0.6	8.5	12	+
F11	313±2.8	8.0±2.2	0.589	99±0.8	8.9	12	+
F12	378±3.5	8.0±1.8	0.640	100±0.4	7.0	12	+
F13	252±3.0	7.5±2.0	0.532	100±0.5	6.5	05	-
F14	378±3.5	8.0±2.5	0.512	100±0.6	6.3	05	-
F15	378±3.5	8.2±1.8	0.611	99±0.4	9.0	12	+

Table 4 Dissolution Data of Tramadol Hydrochloride Tablets Prepared With Ethyl Cellulose in Different Concentrations

TIME(hr)	CUMULATIVE PERCENT DRUG DISSOLVED (n=3±SD)		
	F10	**F11**	**F12**
0.5	27.981±0.58	23.085±0.58	22.319±0.36
1	37.26±0.65	33.69±0.77	35.89±0.980.88
2	44.09±0.59	41.56±0.69	40.61±0.46
3	56.11±0.58	53.35±0.25	52.24±0.58
4	64.93±0.58	60.96±0.89	61.93±0.88
5	76.36±0.58	68.79±0.58	65.27±0.85
6	85.24±1.00	83.97±0.98	78.46±0.88
7	88.1343±0.88	86.319±0.58	85.26±0.85
8	95.2854±0.54	93.1921±0.65	94.72±0.89

Table 5: Dissolution Data of Tramadol Hydrochloride Tablets Prepared With Sodium Cmc in Different Concentrations

TIME (hr)	CUMULATIVE PERCENT DRUG DISSOLVED (n=3±SD)		
	F13	**F14**	**F15**
0.5	26.62±0.58	28.70±0.58	21.42±0.44
1	39.80±0.54	42.53±0.89	26.49±0.68
2	48.66±0.66	53.81±0.87	39.27±0.98
3	64.11±0.77	65.09±0.84	55.22±0.55
4	81.70±0.85	87.84±0.77	61.82±0.84
5	97.53±0.67	99.56±0.95	66.86±0.67
6			74.53±0.52
7			83.82±0.86
8			88.50±1.05
9			93.09±0.85
10			99.82±0.67

Table.6: Release kinetics: Coefficient of correlation (r) values of different batches of Tramadol HCl floating tablets

Formulation	Zero order	First order	Higuchi's	Peppa's
F1	0.920	0.946	0.997	0.996
F2	0.931	0.936	0.997	0.996
F3	0.948	0.957	0.996	0.994
F4	0.949	0.958	0.995	0.991
F5	0.957	0.964	0.996	0.993
F6	0.950	0.958	0.994	0.990
F7	0.937	0.968	0.993	0.992
F8	0.947	0.957	0.994	0.992
F9	0.963	0.972	0.991	0.992
F10	0.932	0.941	0.992	0.981

F11	0.944	0.953	0.990	0.988
F12	0.942	0.955	0.992	0.984
F13	0.957	0.913	0.983	0.978
F14	0.923	0.917	0.981	0.974
F15	0.940	0.971	0.995	0.990

Table.7: Dissolution Parameters of Tramadol Hydrochloride Tablets

	Dissolution Parameters					
Formulation	**n**	**K_0**	**K_1**	**T_{50}**	**T_{75}**	**T_{90}**
F1	0.507	9.375	0.301	2.5	5.8	8.0
F2	0.514	7.775	0.248	3.6	6.8	10.0
F3	0.507	7.604	0.223	3.5	7.5	10.1
F4	0.505	7.424	0.204	3.8	7.5	10.2
F5	0.507	7.268	0.186	4.0	8.1	10.5
F6	0.479	6.593	0.175	4.5	8.5	11.1
F7	0.479	5.861	0.151	4.0	8.5	11.2
F8	0.483	6.563	0.175	4.5	9.3	12.0
F9	0.610	6.762	0.179	5.1	9.1	>12
F10	0.459	10.6	0.354	5	9.5	11.9
F11	0.500	10.43	0.299	2.6	4.8	7.2
F12	0.486	10.32	0.299	2.8	5.5	7.8
F13	0.530	16.94	0.502	2.1	3.5	4.8
F14	0.495	18.92	0.453	2.0	3.8	4.9
F15	0.535	9.431	0.267	2.5	6.0	8.5

Conclusion

Hydrophilic matrix of HPMC could not control the Tramadol release effectively for more than 12 hours. Regulated drug release in first order manner attained in the current study indicates that the matrix tablets of Tramadol hydrochloride prepared using HPMC K100M can successfully be employed as a floating controlled released during delivery system. The optimized formulation F9 (HPMC K100M with concentratin of 200 mg) gave Slow and controlled release of Tramadol hydrochloride over a period of 12hours. This tablets exhibited good floating time for12 hours.

Conflict of Interests

The authors declare no conflict of interest

Funding

This study received no specific funding from public, commercial, or not for profit funding agencies.

AI Tool Declaration

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

Data Availability

Data will be available on request

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